

## Certificate of Analysis

**Product name:** **Levocarnitinum**  
**Batch number / Weight:** **21L02-B04-216326 / 50 G**  
**Analysed according to:** **Ph. Eur.**

| Tests                     | Requirement  | Result  | Unit | Standard remark |
|---------------------------|--|---------|------|-----------------|
| Appearance                | (Almost) white, crystalline powder or colourless crystals, hygroscopic | Conform |      |                 |
| Identification A          | -29,0 - -32,0  | Conform |      |                 |
| Identification B          | Conform  | Conform |      |                 |
| Appearance of solution    | Clear, colourless  | Conform |      |                 |
| pH                        | 6,5 - 8,5  | 7,53    |      |                 |
| Specific optical rotation | -29,0 - -32,0  | -30,2   |      |                 |
| Related substances        | Conform  | Conform |      |                 |
| Impurity A                | <=0,5  | <0,05   | %    |                 |
| Any impurity              | <=0,10   | 0,06    | %    |                 |
| Total impurities A        | <=0,5  | 0,06    | %    |                 |
| Chlorides                 | <=200  | <200    | ppm  |                 |
| Sulphates                 | <=300  | <300    | ppm  |                 |
| Water (Karl Fischer)      | <=1,0  | 0,35    | %    |                 |
| Sulphated ash             | <=0,1  | 0,07    | %    |                 |
| Metallic residues         | CHMP/ICH/353369/2013   | Conform |      | Data producer   |
| Residual solvents         | CPMP/ICH/82 260/06   | Conform |      | Data producer   |
| Assay Levocarnitine       | 98,0 - 102,0   | 99,1    | %m/m |                 |
| TSE/BSE-statement:        | No contamination with TSE/BSE-risk materials                           | Conform |      | Data producer   |

Analysis performed by the authorized lab.

Release:  
 Agnieszka Pszczółka  
 Qualified Person

11-03-2022

Expiration: 23-10-2024

Conclusion: APPROVED

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